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ABBREVIATIONS

Below is a list of common abbreviations that will be used throughout this Investigator's Manual.

ABPI	Association of the British Pharmaceutical Industry
BAC	Bioethics Advisory Committee
CAPA	Corrective Action and Preventive Action
CFR	US Code of Federal Regulations
CIOMS	Council for International Organisations of Medical Sciences
CIRB	SingHealth Centralised Institutional Review Board
CITI	Collaborative Institutional Training Initiative
CRC	Clinical Research Coordinator
CRF	Case Report Form
CRM	Clinical Research Materials
CRU	Clinical Research Unit
CTA	Clinical Trial Authorisation
CTC	Clinical Trial Certificate
CTN	Clinical Trial Notification
DCF	Data Collection Form
DHHS	US Department of Health and Human Services
DNA	Deoxyribonucleic acid
DR	Department Representative
DSMB	Data Safety Monitoring Board
DSRB	Domain Specific Review Board
ECOS	Ethics and Compliance Online System
FCOI	Financial Conflict Of Interest
FDA	US Food and Drug Administration
GCP	Good Clinical Practice
HRPP	Human Research Protection Programme
HBR	Human Biomedical Research
HBRA	Human Biomedical Research Act

HIV	Human Immunodeficiency Virus
HSA	Health Sciences Authority
ICF	Informed Consent Form
ICH	International Council for Harmonisation
ICOI	Institutional Conflict Of Interest
IDE	Investigational Device Exemption
IND	Investigational New Drug Application
IO	Institution Officer
IR	Institution Representative
IRB	Institutional Review Board
MD	Medical Device
MOH	Ministry of Health Singapore
MP	Medicinal Product
NHG Health	NHG Health
NMEC	National Medical Ethics Committee
NUS	National University of Singapore
OHRPP	NHG Health Office of Human Research Protection Programme
PCR	Proper Conduct of Research
PDPA	Personal Data Protection Act
PDPC	Personal Data Protection Commission
PI	Principal Investigator
QA	Quality Assessment
QI	Quality Improvement
REC	NHG Research Ethics Committee
RI	Research Institution
SAE	Serious Adverse Event
SBE	Social, behavioural and educational (modules from CITI)
SDC	Singapore Dental Council
SMC	Singapore Medical Council
SOP	Standard Operating Procedures
STD	Sexually Transmitted Diseases

TP	Therapeutic Product
UPIRTSO	Unanticipated Problems Involving Risks To Subjects or Others
USADR	Unexpected Serious Adverse Drug Reactions